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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/581,184	06/29/2006	Gary A. Anderson	33555-US-PCT	3229

74479 7590 09/30/2008

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EXAMINER	
MOSHER, MARY	
ART UNIT	PAPER NUMBER
1648	
MAIL DATE	DELIVERY MODE
09/30/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/581,184	ANDERSON ET AL.	
	Examiner	Art Unit	
	Mary E. Mosher, Ph.D.	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *01 June 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-18* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-18* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *6/1/06*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Objections

Claims 4, 10, and 17 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claim 1 is drawn to a pathogenic virus. Claim 4 is drawn to an attenuated virus. Since an attenuated virus, by definition, is not pathogenic, then claim 4 is outside the scope of claim 1. This affects dependent claims 10 and 17.

Information Disclosure Statement

The information disclosure statement filed 6/1/2006 fails to comply with 37 CFR 1.98(a)(2), which requires a legible copy of each cited foreign patent document; each non-patent literature publication or that portion which caused it to be listed; and all other information or that portion which caused it to be listed. It has been placed in the application file, but the information referred to therein has not been considered.

Claim Rejections - 35 USC § 112

Biological deposit

Claims 2, 3, 6-8, 13-16, 18 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. These claims specifically require strain PTA-6306, either as an element of

the claimed product or method, or as a material needed to make or to identify the claimed product or method. As a required element it must be known and readily available to the public or obtainable by a repeatable method set forth in the specification, or otherwise readily available to the public. If it is not so obtainable or available, the enablement requirements of 35 U.S.C. § 112, first paragraph, may be satisfied by a deposit of PTA-6306. It is noted that applicants have made a deposit under the terms of the Budapest Treaty, as stated on specification page 9. However, the deposit statement in the specification does not address the public availability of the deposit.

If a deposit is made under the terms of the Budapest Treaty, then an affidavit or declaration by applicants or someone associated with the patent owner who is in a position to make such assurances, or a statement by an attorney of record over his or her signature, stating that the deposit has been made under the terms of the Budapest Treaty and that all restrictions imposed by the depositor on the availability to the public of the deposited material will be irrevocably removed upon the granting of a patent, would satisfy the deposit requirements. See 37 CFR 1.808.

Definiteness

Claims 3, 7, 8, 13-16 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. These claims involve "specifically reactive" or "specifically binds" antibodies. The specification provides no information on the antigenic properties of PTA-6306. For example, it is not disclosed in the specification if

the strain has any antigenic differences from bovine enterovirus type 3 strain PS89. The specification does not contain a definition of "specifically reactive", and the meaning of this phrase is subject to a wide range of interpretation in the art. For example, every antibody reacts specifically with a particular epitope. If the epitope is present on PTA-6306, is that antibody claimed? If the epitope is present on PTA-6306 and also on PS89, is that antibody claimed? The specification does not disclose any epitopes on PTA-6306, and particularly does not disclose any epitopes that are unique to PTA-6306. The absence of a definition of this key term, and the absence of any disclosure of the actual immunological properties of PTA-6306, make it impossible to determine the metes and bounds of the claimed subject matter involving "specifically reactive" materials.

How to make & use the invention

Claims 1-18 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The claims all involve a pathogenic bovine enterovirus. The specification contains much general discussion of pathogenic bovine enteroviruses and discussion of methods of characterization, but the specification provides no actual evidence of pathogenicity for PTA-6306 or any other bovine enterovirus isolate. Those skilled in the art appear to be very skeptical about the pathogenicity of bovine enteroviruses, see as evidence the review by Kahrs et al (Viral Diseases of Cattle, Iowa State University

Press, pp. 135-141, 2001). The specification suggests obtaining pathogenic enterovirus by taking deep nasal swabs, or from lung tissue or nasosinus tissue from "off feeding" animals. Such methods have been used in the prior art to isolate bovine enteroviruses, but the resulting isolates have not been widely considered as pathogenic. See for example Kahrs et al, and Dunne et al (JAVMA 164:290-294, 1974). Therefore, the invention requires the artisan to obtain a pathogenic enterovirus by methods which have failed in the prior art to obtain pathogenic enteroviruses. One isolate is disclosed, but the specification fails to present evidence of its pathogenicity. In the absence of evidence of actual pathogenicity, there is no disclosed or readily apparent use for the claimed bovine enteroviruses, or for related attenuated, inactivated, diagnostic, and immunogenic materials and methods. Considering the state of the art, the limited teachings in the specification, and the absence of working examples illustrating the pathogenicity asserted in the claims, it is concluded that undue experimentation would be required to make the claimed pathogenic bovine enteroviruses, and to use the invention as claimed for either the generic "pathogenic bovine enterolvirus" or the specific isolate PTA-6306.

Written description

Claims 1-17 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed,

had possession of the claimed invention. This is a "written description" rejection, with several aspects.

Claims 1, 3-5, 7-12, and 17 all involve the genus of "pathogenic bovine enterovirus" and attenuated variants thereof. Claim 6 involves attenuated variants of a specific isolate, PTA-6306. As discussed above, those skilled in the art doubt the pathogenicity of bovine enteroviruses. The specification does not describe particular characteristics of a pathogenic bovine enterovirus, and the only enterovirus reduced to practice has not been shown to be pathogenic. Therefore, the specification does not reasonably convey possession of the genus of "pathogenic bovine enterovirus," as claimed. Furthermore, the specification fails to describe with particularity the characteristics of an attenuated variant of a pathogen (of undemonstrated pathogenicity). For these reasons, it is concluded that the specification does not meet the written description requirement for the claimed pathogenic viruses or attenuated derivatives thereof.

Claim 3 is drawn to the genus of pathogenic bovine enteroviruses that are specifically reactive with antibodies made by intranasally inoculating a bovine with PTA-6306. Claims 7 and 8 involve the same genus of viruses. Claims 13-16 involve the genus of monoclonal antibodies that specifically bind to a protein of PTA-6306. As discussed above, it is not apparent from the specification precisely what is meant by "specifically" in this context. The specification discloses reduction to practice of one species of virus in the claimed genus, PTA-6306 itself. The specification does not disclose reduction to practice of any species of antibody in the genus, and provides no

guidance whatsoever as to immunological properties of PTA-6306. Since there is no disclosure of any unique immunological properties of the virus, there is consequently no disclosure of any antibodies that react to those unique epitopes. Therefore, the specification does not reasonably convey possession of a genus of monoclonal or polyclonal antibodies that in some way distinguish PTA-6306 from other bovine enteroviruses, or reasonably convey possession of viruses which react with those antibodies.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 18 is rejected under 35 U.S.C. 102(b) as being anticipated by Zhang et al (Virus Research, 16(3):235-246, 1990). Claim 18 is drawn to a monoclonal antibody that binds a protein of PTA-6306. Zhang discloses monoclonal antibodies that bind to several serogroups of bovine enterovirus. Since the epitope(s) recognized by these antibodies appear to be present on numerous isolates of bovine enterovirus, there is reason to believe that the same epitope(s) would inherently be present on a new isolate, such as PTA-6306. Therefore, the monoclonal antibodies of Zhang are concluded to anticipate the claimed product, inherently if not explicitly.

Claim 1 is rejected under 35 U.S.C. 102(b) as being anticipated by Bovine Enterovirus type 3 strain PS 89, as evidenced by the ATCC catalog. The strain was

originally described in 1974, and has been publicly available for more than one year before the date of applicant's invention. The strain is isolated and purified, and is pathogenic, at least causing abortion in guinea pigs and diarrhea and leukopenia in calves. Therefore, the reference strain meets each and every limitation of the claim.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 2, 3 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Enterovirus type 3 strain PS 89, as evidenced by the ATCC catalog. These claims are drawn to PTA-6306, or a strain cross-reactive with PTA-6306. Although the specification contains numerous pages of prophetic disclosure on how one might isolate, characterize, and use a pathogenic

enterovirus, the specification does not contain any definite information on any of the characteristics of PTA-6306, except to state that it is a pathogenic bovine enterovirus. PS89 is a pathogenic bovine enterovirus. It was obtained from a cow lung, similar to applicant's suggestion to obtain virus from deep nasal swabs or tissue samples. Therefore, as far as can be determined from the specification, PTA-6306 appears to have the same characteristics as PS89, or to be an obvious variant of PS89. Therefore, the burden is shifted to applicant to show that the claimed virus is different from PS89 in some nonobvious manner. Patent owner's burden under the circumstances presented herein was described in In re Best, 562 F.2d 1252, 1255, 195 USPQ 430, 433-434 (CCPA 1977) as follows:

> Where, as here, the claimed and prior art products are identical or substantially identical, or are produced by identical or substantially identical processes, the PTO can require an applicant to prove that the prior art products do not necessarily or inherently possess the characteristics of his claimed product. . . . Whether the rejection is based on `inherency' under 35 U.S.C. § 102, on `prima facie obviousness' under 35 U.S.C. § 103, jointly or alternatively, the burden of proof is the same, and its fairness is evidenced by the PTO's inability to manufacture products or to obtain and compare prior art products [footnote omitted].

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mary E. Mosher, Ph.D. whose telephone number is 571-272-0906. The examiner can normally be reached on varying dates and times; please leave a message.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on 571-272-0974. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Mary E Mosher, Ph.D./
Primary Examiner, Art Unit 1648

9/26/08